

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 39-55 are pending in the present application. Claims 19-38 have been canceled. Support for claims 39-55 can be found in previously pending claims 19-38 and generally throughout the specification.

In particular, the Examiner's attention is respectfully directed to independent claims 39 and 52. Support for claim 39 may be found in previously pending claims 19 and 34. Claim 39 recites a ratio between omega-3 fatty acids (EPA and DHA) and omega-6 fatty acids (DHGLA and AA). Additional support for this recitation may be found in the present specification on page 6, line 27.

As to claim 52, claim 52 recites the presence of at least phosphatidylserine (PS) and phosphatidylinositol (PI) plus phosphatidylcholine (PC) and phosphatidylethanolamine (PE). Support for claim 52 may be found in claim 24. The recitation that PI may be substituted for PS may also be found in the Examples of the present specification.

In the outstanding Official Action, claims 19-38 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicants regard as the invention.

In imposing the rejection, the Official Action alleged that claim 19 was indefinite for reciting several different transitional-type phrases. Applicants believe that claims 39-55 have been drafted in a manner so as to eliminate any confusion as to the recited transitional phrases.

Claim 19 was also rejected for reciting that fraction (a) requires "at least one of" several recited fatty acids, while also reciting a ratio between recited fatty acids. Claim 39 has been drafted so as to recite that the ratio of the total amount of EPA + DHA + DHGLA + AA to the total amount of linoleic acid and α -linolenic acid is above 0.4:1. Moreover, the weight ratio of the total amount of EPA + DHA to the total amount of DHGLA + AA is in the range from 2.5:1 to 5.5:1. The ratios do not require that each component be present. Indeed, the ratios are recited in terms of the total amount of the long chain polyunsaturated fatty acids that are present in the claimed composition. Indeed, applicants believe that all of the claims have been drafted in a manner so that the recited ratios are definite to one skilled in the art.

Claim 27 was rejected as it was allegedly unclear if fraction (c) comprised zinc and copper or further comprised zinc

and copper. It is believed the claims have been drafted in a manner so as to obviate this rejection.

Claim 35 was rejected for reciting several transitional-type phrases. However, as noted above, applicants believe that claims 39-55 have been drafted in a manner so that the transitional phrases are plainly recited and the scope of the claims are definite to one skilled in the art.

Thus, in view of the above, applicants believe that claims 39-55 are definite to one of ordinary skill in the art.

Claims 19-20, 22, 23, 26, 30, 31, and 33-36 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN 4,810,497, DELLA VALLE et al. 4,595,680 and FUGH-BERMAN et al. This rejection is respectfully traversed.

Applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fails to disclose or suggest the claimed invention. HORROBIN describes a long-chain fatty acid composition supplying 20 mg to 10 g of a total amount of EPA + DHA + D(H)GLA + AA relative to the total amount of 2-30 g of LA + ALA (see column 2, lines 55-59). The ratio of this combination is roughly 0.01:1 to 0.33:1, a ratio that is lower than the claimed ratio. Thus, HORROBIN fails to teach the claimed ratio. Indeed, HORROBIN actually teaches away from the claimed ratio.

The Examiner's attention is also directed to Example 2 of HORROBIN, wherein a ratio of EPA + DHA: DGLA + AA is 1:1. Once again, this is a ratio far below the range of 2.5:1 to 5.5:1 recited in claim 39. Indeed, the remaining compositions disclosed by HORROBIN are even further away from the claimed range.

In an effort to remedy the deficiencies of HORROBIN, the outstanding Official Action cites to DELLA VALLE et al. However, DELLA VALLE et al. do not teach the claimed amounts or ratios of long-chain fatty acids that may be administered to an individual.

In a further effort to remedy the deficiencies of HORROBIN and DELLA VALLE et al., the Official Action cites to FUGH-BERMAN et al. FUGH-BERMAN et al. teach that DHA and EPA, but not AA and DHGLA, may be added to a dietary supplement. However, at best, the teachings of FUGH-BERMAN et al. are speculative in nature. Indeed, FUGH-BERMAN et al. teach that more research should be conducted before natural products can be administered as psychotherapeutic agents (abstract). Moreover, applicants note that FUGH-BERMAN et al. fail to teach or even mention the claimed Ω -3/ Ω -6 ratio.

As a result, applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fails to teach the claimed invention. Indeed, applicants

respectfully submit that none of the publications even provide the necessary motivation or a reasonable expectation of success of combining and modifying their respective teachings to obtain the claimed invention.

Moreover, the Examiner is respectfully reminded that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of the variable might be characterized as routine experimentation. *In re Antonie* 559, F.2d 618, 195 USPQ 6 (CCPA 1977). As noted above, the cited publications fail to teach the claimed amounts and ratios of the claimed invention. In fact, while the cited publications may teach some of the individual components utilized by the claimed invention, the publications do not even refer to the claimed components in terms of a ratio as set forth in the claimed invention.

Moreover, applicants note that the outstanding Official Action acknowledges on page 5 that HORROBIN and DELLA VALLE et al. teach that the disclosed fatty acids and phospholipids should be added in specific amounts to their respective compositions. As a result, applicants believe that the cited publications fail to show that any of the claimed amounts and ratios are simply a matter of routine experimentation. In fact, the cited publications actually teach distinctly lower amounts.

As a result, applicants submit that the Official Action fails to show that one of ordinary skill in the art would consider the claimed amounts and ratios as result-effective variables.

Thus, in view of the above, applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. fails to render obvious the claimed invention.

Claims 19-20, 22-24, 26, 30, 31, 33-36 and 38 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and TAIYO FISHERY CO., LTD. This rejection is respectfully traversed.

Applicants respectfully submit that the TAIYO FISHERY CO., LTD. publication fails to remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. Indeed, the TAIYO FISHERY CO., LTD. publication does not discuss long-chain fatty acids.

Thus, applicants believe that the proposed combination fails to render obvious the claimed invention.

Claims 19-23, 26, 30, 31 and 33-37 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and YU et al. 5,177,082. This rejection is respectfully traversed.

Applicants note that YU et al. are silent as to long-chain fatty acids. As a result, applicants believe that YU et

al. fail to remedy the deficiencies of the above-identified publications.

As a result, applicants believe that the combination of HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and YU et al. does not render obvious claims 39-55.

Claims 19-20, 22, 23, 25, 26, 30, 31, and 33-36 were rejected under 35 USC 103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and SMITH et al. 6,008,221. This rejection is respectfully traversed.

SMITH et al. fail to remedy the deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al. SMITH et al. neither disclose nor suggest the amounts and ratios as set forth in the claimed invention.

Thus, applicants believe that the proposed combination fails to render obvious claims 39-55.

Claims 19-20, 22, 23, 26, 27, 31 and 33-36 were rejected under 35 USC 103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and HUTTERER 4,837,219. This rejection is respectfully traversed.

HUTTERER fails to disclose or suggest the administration of long-chain fatty acids as set forth in the claimed invention for treating Alzheimer's disease. Moreover, HUTTERER fails to teach any of the claimed amounts and ratios. Thus, applicants believe that HUTTERER fails to remedy the

deficiencies of HORROBIN, DELLA VALLE et al. and FUGH-BERMAN et al.

Thus, applicants believe that the proposed combination of HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and HUTTERER does not teach the claimed invention.

Claims 19-20, 22, 23, 25-27 and 30-36 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al., SMITH et al., HUTTERER and GLICK 5,004,615. This rejection is respectfully traversed.

While GLICK may teach the administration of dietary supplements for preventing and controlling dementia and memory loss, GLICK fails to disclose or suggest the administration of long-chain fatty acids. Moreover, GLICK does not remedy any of the deficiencies of HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al., SMITH et al. and HUTTERER.

As a result, applicants believe that the proposed combination fails to render obvious the claimed invention.

Claims 19-20, 22, 23, 26, 28-31 and 33-36 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, DELLA VALLE et al., FUGH-BERMAN et al. and RABIEN (DE 4309217). This rejection is respectfully traversed.

While the outstanding Official Action contends that RABIEN teaches a composition comprising alpha lipoic,

panthothenic acid and vitamin E for treating Alzheimer's disease, RABIEN is silent as to the administration of long-chain fatty acids. Moreover, RABIEN fails to disclose or suggest any of the claimed amounts or ratios.

As a result, applicants believe that RABIEN fails to remedy the deficiencies of the above-identified publications and request that the rejection be withdrawn.

At this time, applicants respectfully request that the Examiner provide a full citation to the case *In re Sussman*. Applicants believe that the application is in condition for allowance for the reasons noted above. However, they did find the abbreviated citation to be insufficient and request that the full citation be provided.

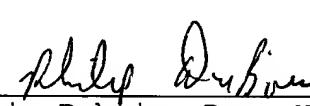
In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance with claims 39-55, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

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Amdt. dated February 25, 2004
Reply to Office Action of August 25, 2003
Docket No. 2001-1165

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R. §1.17.

Respectfully submitted,

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